PATENT COOPERATION TREATY

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PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 15131/PCX019	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International application No. **PCT/NZ 98/00147**	International filing date *(day/month/year)* 6 October 1998	Priority Date *(day/month/year)* 10 October 1997

International Patent Classification (IPC) or national classification and IPC

Int. Cl.[6] A61D 7/00, A61F 6/14

Applicant

DUIRS NZ LIMITED et al.

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   [X] This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheet(s).

3. This report contains indications relating to the following items:

I	[X]	Basis of the report
II	[ ]	Priority
III	[ ]	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	[ ]	Lack of unity of invention
V	[X]	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	[ ]	Certain documents cited
VII	[X]	Certain defects in the international application
VIII	[ ]	Certain observations on the international application

Date of submission of the demand	Date of completion of the report
13 April 1999	12 January 2000
Name and mailing address of the IPEA/AU	Authorized Officer
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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/NZ 98/00147

I. Basis of the report

1. With regard to the **elements** of the international application:*

- [ ] the international application as originally filed.
- [X] the description, pages **1 to 12,** as originally filed,
  pages , filed with the demand,
  pages , filed with the letter of .
- [X] the claims, pages , as originally filed,
  pages , as amended (together with any statement) under Article 19,
  pages **13,** filed with the letter of **5 January 2000**
  pages **14, 15,** filed with the letter of **17 November 1999.**
- [X] the drawings, pages **1/2 to 2/2,** as originally filed,
  pages , filed with the demand,
  pages , filed with the letter of .
- [ ] the sequence listing part of the description:
  pages , as originally filed
  pages , filed with the demand
  pages , filed with the letter of .

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language which is:

- [ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- [ ] the language of publication of the international application (under Rule 48.3(b)).
- [ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, was on the basis of the sequence listing:

- [ ] contained in the international application in written form.
- [ ] filed together with the international application in computer readable form.
- [ ] furnished subsequently to this Authority in written form.
- [ ] furnished subsequently to this Authority in computer readable form.
- [ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- [ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. [ ] The amendments have resulted in the cancellation of:
   - [ ] the description, pages
   - [ ] the claims, Nos.
   - [ ] the drawings, sheets/fig.

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report*

V. Reasoned statement under Article 35(2) with regard to n velty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1 to 16	YES
	Claims		NO
Inventive step (IS)	Claims	1 to 16	YES
	Claims		NO
Industrial applicability (IA)	Claims	1 to 16	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Claims 1 - 16:

Claims 1 to 16 meet the requirements of PCT Articles 33(2)-(4). None of the prior art documents, or obvious combination thereof, disclose a substance delivery device having at least two resilient arms that are capable of receiving and releasing substance delivery means. The closest art of:

WO 88/04544 A (KURZ)

is not capable of releasing the substance delivery means. Claims 1 to 16 are therefore considered novel and inventive.

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claims 15 and 16 do not comply with Rule 6.2(a) because they rely on references to the description and drawings.

CLAIMS:

1. A substance delivery device for insertion into a body, said device includes a support frame having at least two resilient arms which retain said device in the body cavity, wherein each resilient arm is capable of receiving and releasing a substance delivery means capable of releasing substance into the said body cavity.

2. A substance delivery device as claimed in claim 1, wherein the said substance is a drug.

3. A substance delivery device as claimed in either 1 or claim 2 wherein the said device is an intra-vaginal release device.

4. A substance delivery device as claimed in claim 3 wherein the substance is released from the substance delivery means through osmosis.

5. A substance delivery device as claimed in any one of claims 1 to 4 wherein the substance delivery means are rounded.

6. A substance delivery device as claimed in any one of claims 1 to 5 wherein the substance delivery means is flexibly attached to the arm.

7. A substance delivery device as claimed in claim 6 wherein the substance

delivery means is attached to the arm by a ball and socket mechanism.

8. A substance delivery means for attachment to a substance delivery device as claimed in any one of claims 1-7.

9. A substance delivery device as claimed in any one of claims 1 to 7 wherein the support frame is in the form of a wish bone.

10. A substance delivery device as claimed in claim 9 wherein the arms are biased outward from a central section of the support frame.

11. A substance delivery device as claimed in either claim 9 or claims 10 characterised in that the support frame is made of nylon.

12. A substance delivery device as claimed in any one of claims 9 to 11 to characterised in that the arms are sufficiently pliable to be moved together to allow the substance delivery device to be effectively compressed.

13. A substance delivery device as claimed in any one of claims 9 to 12 wherein the arms are capable of interlocking for removal or insertion.

14. A substance delivery device as claimed in any one of claims 9 to 13 characterised in that the support frame includes a locator to enable the substance delivery device to be readily located and removed from *in situ*.

15. A substance delivery device as herein described with reference to and as illustrated by the accompanying drawings.

16. A substance delivery means substantially as herein described with reference to and as illustrated by the accompanying drawings.

CLAIMS:

1. A substance delivery device.

characterised in that

the device includes a support frame capable of receiving and releasing a substance delivery means which is capable of releasing substance into a body cavity.

2. A substance delivery device wherein the substance is a drug.

3. A substance delivery device as claimed in either claim 1 or claim 2 in the form of an intravaginal release device.

4. A substance delivery device as claimed in any one of claims 1 to 3 wherein the substance delivery means is in the form of a pod.

5. A substance delivery device as claimed in claim 4 wherein the substance is released from the pod through osmosis.

6. A substance delivery device as claimed in either claim 4 or claim 5 wherein the pods are rounded.

7. A substance delivery device as claimed in any one of claims 1 to 6 wherein the substance delivery means is flexibly attached to the device.

8. A substance delivery device as claimed in claim 7 wherein the substances delivery means is attached by a ball and socket mechanism.

9. A pod for attachment to a substance delivery device as claimed in any one of claims 4 to 8.

10. A support frame for a drug delivery device having at least one curved arm which can support a substance delivery means.

11. A support frame as claimed in claim 10 wherein the curved arm provides pliability.

12. A support frame as claimed in claimed in either claim 10 or claim 11 wherein the curved arm provides tension.

13. A support frame as claimed in any one of claims 10 to 12 which has two arms.

14. A support frame as claimed in any one of claims 10 to 13 wherein the support frame is in the form of a wishbone.

15. A support frame as claimed in any one of claims 10 to 14 wherein the arm or arms are biased outwards from the body of the support frame.

16. A support frame as claimed in any one of claims 10 to 15 characterised in that the support frame is made of nylon.

17. A support frame as claimed in any one of claims 10 to 16 characterised in

the arms are sufficiently pliable to be moved together to allow the substance delivery device to be effectively compressed.

18. A support frame as claimed in any one of the claims 10 to 17 wherein the arms are capable of interlocking for removal or insertion.

19. A support frame as claimed in any of the claims 10 to 18 which are capable of receiving a substance delivery device or devices at the distal end of the arm or arms.

20. A support frame as claimed in any one of claims 10 to 19 characterised in that support frame includes a locator to enable the substance delivery device to be readily located and removed from *in situ*.

21. A substance delivery device substantially as herein described with reference to and as illustrated by the accompanying drawings.

22. A pod substantially as herein described with reference to and as illustrated by the accompanying drawings.

23. A support frame substantially as herein described with reference to and as illustrated by the accompanying drawings.

AMENDED CLAIMS

[received by the International Bureau on 20 May 1999 (20.05.99);
original claims 1-23 replaced by amended claims 1-22 (3 pages)]

1. A substance delivery device.

characterised in that

the device includes a support frame capable of receiving and releasing a substance delivery means which is capable of releasing substance into a body cavity,

wherein the substance delivery means is in the form of a pod which houses or incorporates the substance to be delivered.

2. A substance delivery device wherein the substance is a drug.

3. A substance delivery device as claimed in either claim 1 or claim 2 in the form of an intravaginal release device.

4. A substance delivery device as claimed in claim 3 wherein the substance is released from the pod through osmosis.

5. A substance delivery device as claimed in claim 4 wherein the pods are rounded.

6. A substance delivery device as claimed in any one of claims 1 to 5 wherein the substance delivery means is flexibly attached to the device.

7. A substance delivery device as claimed in claim 6 wherein the substances delivery means is attached by a ball and socket mechanism.

8. A pod for attachment to a substance delivery device as claimed in any one of claims 4 to 7.

9. A support frame for a drug delivery device having at least one curved arm which can support a substance delivery means.

10. A support frame as claimed in claim 9 wherein the curved arm provides pliability.

11. A support frame as claimed in claimed in either claim 9 or claim 10 wherein the curved arm provides tension.

12. A support frame as claimed in any one of claims 9 to 11 which has two arms.

13. A support frame as claimed in any one of claims 9 to 12 wherein the support frame is in the form of a wishbone.

14. A support frame as claimed in any one of claims 9 to 13 wherein the arm or arms are biased outwards from the body of the support frame.

15. A support frame as claimed in any one of claims 9 to 14 characterised in that the support frame is made of nylon.

16. A support frame as claimed in any one of claims 9 to 15 characterised in the arms are sufficiently pliable to be moved together to allow the

substance delivery device to be effectively compressed.

17. A support frame as claimed in any one of the claims 9 to 16 wherein the arms are capable of interlocking for removal or insertion.

18. A support frame as claimed in any of the claims 9 to 17 which are capable of receiving a substance delivery device or devices at the distal end of the arm or arms.

19. A support frame as claimed in any one of claims 9 to 18 characterised in that support frame includes a locator to enable the substance delivery device to be readily located and removed from *in situ*.

20. A substance delivery device substantially as herein described with reference to and as illustrated by the accompanying drawings.

21. A pod substantially as herein described with reference to and as illustrated by the accompanying drawings.

22. A support frame substantially as herein described with reference to and as illustrated by the accompanying drawings.

ARTICLE 19 AMENDMENTS

AMENDED CLAIMS

[received by the International Bureau on 20 May 1999 (20.05.99);
original claims 1-23 replaced by amended claims 1-22 (3 pages)]

1. A substance delivery device.

characterised in that

the device includes a support frame capable of receiving and releasing a substance delivery means which is capable of releasing substance into a body cavity,

wherein the substance delivery means is in the form of a pod which houses or incorporates the substance to be delivered.

2. A substance delivery device wherein the substance is a drug.

3. A substance delivery device as claimed in either claim 1 or claim 2 in the form of an intravaginal release device.

4. A substance delivery device as claimed in claim 3 wherein the substance is released from the pod through osmosis.

5. A substance delivery device as claimed in claim 4 wherein the pods are rounded.

6. A substance delivery device as claimed in any one of claims 1 to 5 wherein the substance delivery means is flexibly attached to the device.

7. A substance delivery device as claimed in claim 6 wherein the substances delivery means is attached by a ball and socket mechanism.

8. A pod for attachment to a substance delivery device as claimed in any one of claims 4 to 7.

9. A support frame for a drug delivery device having at least one curved arm which can support a substance delivery means.

10. A support frame as claimed in claim 9 wherein the curved arm provides pliability.

11. A support frame as claimed in claimed in either claim 9 or claim 10 wherein the curved arm provides tension.

12. A support frame as claimed in any one of claims 9 to 11 which has two arms.

13. A support frame as claimed in any one of claims 9 to 12 wherein the support frame is in the form of a wishbone.

14. A support frame as claimed in any one of claims 9 to 13 wherein the arm or arms are biased outwards from the body of the support frame.

15. A support frame as claimed in any one of claims 9 to 14 characterised in that the support frame is made of nylon.

16. A support frame as claimed in any one of claims 9 to 15 characterised in the arms are sufficiently pliable to be moved together to allow the

substance delivery device to be effectively compressed.

17. A support frame as claimed in any one of the claims 9 to 16 wherein the arms are capable of interlocking for removal or insertion.

18. A support frame as claimed in any of the claims 9 to 17 which are capable of receiving a substance delivery device or devices at the distal end of the arm or arms.

19. A support frame as claimed in any one of claims 9 to 18 characterised in that support frame includes a locator to enable the substance delivery device to be readily located and removed from *in situ*.

20. A substance delivery device substantially as herein described with reference to and as illustrated by the accompanying drawings.

21. A pod substantially as herein described with reference to and as illustrated by the accompanying drawings.

22. A support frame substantially as herein described with reference to and as illustrated by the accompanying drawings.

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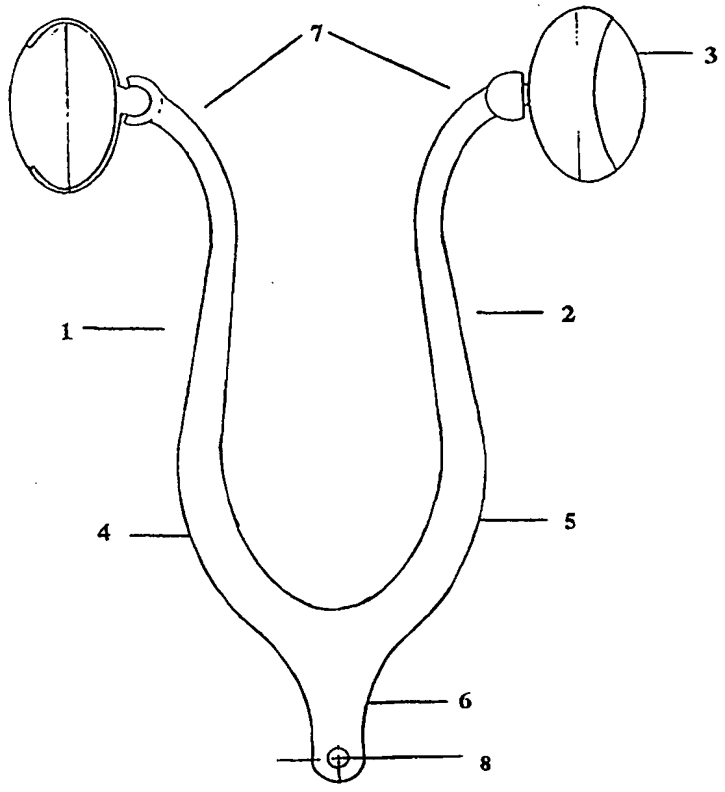
(54) Title: DRUG DELIVERY SYSTEM

(57) Abstract

The present invention relates to a substance delivery device particularly useful for delivering drugs into body cavities. The device in preferred embodiments has a wishbone shape (1, 2, 4, 5, 6, 7) and attachable pods (3) which deliver the substance.



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DRUG DELIVERY SYSTEM

TECHNICAL FIELD

This invention relates to a substance delivery system.

Reference throughout the specification shall be made to the use of the present invention as a drug delivery system for use in animal body cavities, such as the vagina.

Should be appreciated however that the present invention can be used to deliver substances other than drugs and can be used in relation to humans and in other body cavities, for example the rumen, ears, mouth and so forth.

Drug delivery systems are used extensively in controlled breeding and reproductive management. Although considerable research has been invested in the design of these devices, there are still problems associated with them.

Firstly, these devices are required to be retained within the body cavity for the slow release of drugs over a period of time. To facilitate this, various arms and projections have been built into the device which can either engage with the walls of the body cavity, or make the device wide enough such that when in the body cavity the device cannot naturally exit the animal through the entrance orifice.

Major problems with the provision of such arms or projections is that they can irritate or even rupture the lining of the body cavity, causing distress to the animal and providing a site for possible infection. Yet another problem with these projections is that in order for the device to be inserted into the animal, the device will need to be considerably smaller than it is when the projections are fully extended. Thus, the device needs to be designed so the projections

can be retracted or folded away during insertion and removal of the device.

A major problem with drug delivery devices is that traditionally they have been manufactured with the drug impregnated into the material from which the device is made. Typically, this material is in many instances a matrix of silicone.

To manufacture devices from drug impregnated silicone is expensive.

A further disadvantage of using a drug impregnated device is that it is very difficult to dispose. For example, the hormones used in reproductive management are required to be disposed in accordance with heavily regulated environmental procedures. As it is always possible that the drug within the silicone matrix had not been fully delivered to the animal when the device is removed, the whole device will have to be disposed as the whole device is the drug delivery system.

It would be desirable if the devices could be reused.

Another problem with the devices is that they have a specific dose rate which cannot be readily changed. Further with these devices, the treatment cannot be changed or customised according to requirements. For instance, animals at the heavier end of the species weight range may require a dose supplement or a type of breed may vary in size and require a dose change.

It would be desirable if there could be provided a drug delivery device for use inside body cavities which was easy to insert, readily retained within the cavity without irritation to the cavity walls, was reusable, could allow for differing treatments and was comparatively inexpensive.

BACKGROUND ART

It is an object of the present invention to address the foregoing problems or at least to provide the public with a useful choice.

Further aspects and advantages of the present invention will become apparent from the ensuing description which is given by way of example only.

DISCLOSURE OF INVENTION

According to one aspect of the present invention there is provided a substance delivery device

characterised in that

the device includes a support frame capable of receiving and releasing a substance delivery means which is capable of releasing substance into a body cavity.

According to another aspect of the present invention there is provided a pod for use with the support frame as described above.

The substance delivery device should now be referred to as a drug delivery device such as an intravaginal release device.

It should be appreciated however that a device in accordance with the present invention can be adapted for use in other body cavities, such as the rumen, the auditory system and so forth. It should also be appreciated that the present invention can be used in both humans and animals.

Further, it should be appreciated that the substance being delivered can be in a variety of forms e.g. liquid, solid bullets, powder, gel and so forth.

The support frame may come in a number of configurations. The main purpose of the support frame is to hold the substance delivery pods in such a manner that they can deliver the substance effectively to the body cavity.

Other requirements of the support frame is that it is naturally retained within the body cavity when required for the delivery of substance, but can also be readily inserted and removed.

The applicant has designed support frames with a number of configurations which meet the above criteria. One particular set of designs the applicant has arrived at has at least one arm which is pliable in movement situations, that maintains a tension across the length of the arm.

According to an alternate aspect of the present invention there is provided a support frame for a drug delivery device having at least one curved arm which can support a substance delivery means.

In some embodiments of the substance delivery means described immediately above may not be removable pods but fixed to the support frame.

However, reference throughout this specification will now be made to the drug delivery device as having removable substance delivery means in the form of pods.

It should be appreciated the prior art devices were fairly inflexible having straight arms rigidly fixed to the main body of this device when *in situ*. In contrast, the applicant has found that a curved arm or arms give considerable pliability and/or tension.

For ease of reference, throughout the specification the support frames shall be referred to as having two arms.

It should be appreciated however that the present invention can have any number of arms and that two arms is merely just one form of a preferred embodiment.

The applicant believes that having arms which are pliable in movement situations means that the device is less harsh on the interface with the mucosal membrane in the vagina. For example, animal movement or change of position will enable the device to flex accordingly to facilitate animal comfort and yet maintain retention integrity characteristics.

One way by which such a design can be achieved is to create a "wishbone" shape. That is, a comparatively short joining piece or base and two arms which curve firstly outwards from the base and then inwards to provide a substantially S-shaped arms.

If the arms curve away from the base so as to form the outline of the bowl, there is no tension where the arms connect to the base. However, there is tension throughout the arms provided by the double curve of the S-shape.

The lack of tension at the base means that the arms can still move with respect to the base if required. However the tension along the length of the arms can cause the arms to bias outwards from the body of the support frame causing the arms or the substance delivery pods attached to arms to extend outwards toward the mucosal membrane, and in some cases exposing the surface of the pods to the mucosal membrane.

It should be noted to here that the mucosal membrane is very effective at transferring drugs to the body. And, while it is not a necessity, it can be beneficial to drug delivery.

It should be appreciated that other configurations are envisaged. For example, one embodiment present invention may be in the shape of a part circle, such as a "bicycle clip" configuration which requires no base: but still has the tension and pliability in the arms. Other embodiments may have the arms, not curving away from the base in a bowl shape, but curving in the opposite direction.

One embodiment may be a single curved arm with one or more pods attached to it.

It should be appreciated that the base can be used to locate and remove the device.

There is now greater choice in the material from which the support frame can be made. This is because present invention obviates the need to impregnate the support frame with the substance to be delivered. This is because in preferred embodiments the drug delivery pods are attachable and removable from the support frame. Thus, manufacture of the support frame is quite independent of the drug delivery system.

In further embodiments however the support frame is made of a plastics material such as nylon which is readily moulded, flexible and is physiologically friendly and reusable. Other materials may of course be used.

The term pod should not be seen as limiting as is intended to mean any article which can be attached to or detached from the support frame and capable of releasing substances such as drugs.

In one embodiment of the present invention the pods may consist only of the drug itself moulded into a shape that can interact with the support frame.

However, preferred embodiments of the present invention the pods are devices

which house or incorporatethe substance to be delivered.

The pods may release the substances into the body cavity by a variety of means. In one embodiment, this may be through a simple process of osmosis of the drug passing through a membrane on the pod.

In other embodiments it may be a device in the pod which applies pressure to the drug pushing it out of the pod for instance, through micropores.

In other embodiments there may be electronically controlled release of the substance.

The pods can take any suitable shape. However, it is preferable that the pods do not have projections which could irritate the lining of the body cavity. Instead, it is envisaged that the outer surfaces of the pods are smooth and possibly rounded. In one embodiment, the pods are substantially egg shaped.

Pods may be made from any suitable material. In one embodiment, the pods may comprise a cellulose matrix which allows the leaching of drugs contained within the matrix into the fluids of the body cavity.

The pods maybe attached to the support frame by a variety of means.

For example, there may be a complementary plug and socket between the pod and the support frame allowing the pod to be readily attached to and subsequently detached from the frame. This would enable reloading of the device to prolong a treatment. The design would also enable concurrent treatments of different drugs or substances to be applied from two or more pods through different stages of a treatment cycle by removing the device and placing new pods for immediate reinsertion thereby creating no disruption to the current treatment cycle and similarly the same treatment may be prolonged

by replacing pods.

Thus, the present invention can provide two or more co-current treatments, two or more sequential treatments or prolong a single treatment. All of which are achievable by the ability to replace pods.

In another embodiment the pod will be configured so as to have a portion of the pod slide into a groove on the support frame (or vice versa).

Other attachment mechanisms may be the mating of uneven surfaces (such as in Velcro™).

Another method may the use of a suitable adhesive.

However, in preferred embodiments the pod is flexibly attached to the support frame allowing full movement of the pod with respect to the support frame. This enables the surfaces of the pod to move gently against the lining of the body cavity (or not at all) even if there is a violent movement of the support frame holding the pods.

It should be appreciated that if the pods have a curved surface as previously described, and the arms are tensioned gently outwards, the flexible attachment allows the surface of the pod to gently contact the mucosal membrane of the vagina without irritation allowing ready transfer of the drugs contained within the pods. It should be noted that some treatments will be enhanced by mucosal membrane contact whereas other treatments can be transmitted effectively through delivery into the vaginal mucosa and fluids.

It is envisaged that there are many ways by which the flexible attachment may be achieved.

In one embodiment this is by a ball and socket arrangement allowing three dimensional movement of the pod with respect to the support frame.

It should be seen that the tensioning of the arms outwards enables the device to be retained in the body cavity when *in situ*. However, the use of pliable arms means that the arms can be moved to allow the device to be effectively compressed to allow ready insertion and withdrawal of the device through the orifice to the body cavity.

In one embodiment, the device is capable of having its arms wrapped around itself or merely compressed together.

In another embodiment to the present invention the arms are capable of interlocking for removal or insertion.

For example, the main body of the arms may be designed such that the stem is made in two adjacent webs that are joined by connecting braces at regular intervals. The adjacent arms of the device facing one another may be slightly offset. This enables the arms to be forced together so the upper arch of wishbones on adjacent webs intertwine to enable the adjacent pods to close together to the narrowest position.

If webs are used, then the device has less material giving a lighter frame and therefore is less likely to cause adverse tissue reactions.

It should be appreciated that the pods can be positioned anywhere in relative to the support frame. However, preferred embodiments of pods are attached at or near the distal end of the arms of the support frame. In some embodiments there may be more than one pod on an arm.

In preferred embodiments of the present invention there is provided a locator

to enable the device *in situ* to be readily located and removed from the animal. This locator in some instances may be an aperture.

It can be seen that the present invention has considerable advantages over the prior art.

Usage of attachable pods enable the support frame of the device to be readily reused which leads to economical savings.

Further, only the pods need to be disposed of giving environmental advantages. Furthermore, the pods can be assessed for residual drug containment and if necessary be disposed according to environmental safety requirements if treatment has not depleted the drug.

The ability to remove pods means that treatment of the animal or human can be changed in the treatment through the removal of the device and the substitution of a pod or more.

Treatments can also be customised with different pods use, perhaps containing different drugs or different dosage rates.

The flexible attachment of the pods to the support frame means that the pods are free moving and able to orientate themselves in accordance with mucosal membrane movement and device orientation. This enables the pods to provide interface with the mucosal membrane in some instances enhance the delivery and transmission of drugs and nutrients.

The wishbone configuration of preferred embodiments provides a gentle tensioning of the arms in comparison with rigid devices used previously.

Manufacture of the support frame is considerably easier than previously as there is no need to consider the impregnation of drugs into material from which the support frame is manufactured.

Finally, the present invention allows for ready insertion and removal.

Aspects of the present invention will now be described by way of example only with reference to the accompanying drawings in which:

Figure 1 diagrammatic view of substance delivery device in accordance with one embodiment on the present invention, and

Figure 2 diagrammatic drawing of the device in figure 1 in an insertion/removal configuration.

With respect to the figures, there is illustrated a drug system delivery device generally indicated by arrow 1.

The device 1 includes a support frame 2 attached to which are substance delivery pods 3.

The support frame 2 is in the form of a wishbone having two arms 4 and 5 substantially S-shaped connected to an elongated base 6.

The base 6 contains a locator, in the form of an aperture 8, for easy location and removal of the device. Note the base is not associated with any flexing which only occurs along the S-shaped arms.

The arms 4 and 5 are curved in such a manner that when *in situ* (refer Figure 1) the distal ends of the arms 7 are biased outwards.

It is envisaged that the configuration of the arms and the flexibility of the material from which the support frame will be made will enable the arms to move in such a fashion so as to cross-over as illustrated in Figure 2. There may be provided webbing (not shown) to interlock the arms. This cross-over configuration allows for ready insertion and removal of the device.

The pods 3 are housings which contain a drug delivered into the body cavity. In this embodiment, housing of pods 3 is cellulose or an appropriate matrix.

The pods 3 are attached to the arms 4 and 5 by a flexible attachment in the form of a ball and socket (not clearly shown).

It can be seen that the curved outer shape of the pods 3 in combination with the biasing of the arms 4 and 5 and the flexible attachment allows free movement of the pods against the mucosal membrane without irritating the membrane.

Aspects of the present invention are described by way of example only and it should be appreciated that modifications and additions may be made thereto without departing from the scope of the appended claims.

CLAIMS:

1. A substance delivery device.

characterised in that

the device includes a support frame capable of receiving and releasing a substance delivery means which is capable of releasing substance into a body cavity.

2. A substance delivery device wherein the substance is a drug.

3. A substance delivery device as claimed in either claim 1 or claim 2 in the form of an intravaginal release device.

4. A substance delivery device as claimed in any one of claims 1 to 3 wherein the substance delivery means is in the form of a pod.

5. A substance delivery device as claimed in claim 4 wherein the substance is released from the pod through osmosis.

6. A substance delivery device as claimed in either claim 4 or claim 5 wherein the pods are rounded.

7. A substance delivery device as claimed in any one of claims 1 to 6 wherein the substance delivery means is flexibly attached to the device.

8. A substance delivery device as claimed in claim 7 wherein the substances delivery means is attached by a ball and socket mechanism.

9. A pod for attachment to a substance delivery device as claimed in any one of claims 4 to 8.

10. A support frame for a drug delivery device having at least one curved arm which can support a substance delivery means.

11. A support frame as claimed in claim 10 wherein the curved arm provides pliability.

12. A support frame as claimed in claimed in either claim 10 or claim 11 wherein the curved arm provides tension.

13. A support frame as claimed in any one of claims 10 to 12 which has two arms.

14. A support frame as claimed in any one of claims 10 to 13 wherein the support frame is in the form of a wishbone.

15. A support frame as claimed in any one of claims 10 to 14 wherein the arm or arms are biased outwards from the body of the support frame.

16. A support frame as claimed in any one of claims 10 to 15 characterised in that the support frame is made of nylon.

17. A support frame as claimed in any one of claims 10 to 16 characterised in

the arms are sufficiently pliable to be moved together to allow the substance delivery device to be effectively compressed.

18. A support frame as claimed in any one of the claims 10 to 17 wherein the arms are capable of interlocking for removal or insertion.

19. A support frame as claimed in any of the claims 10 to 18 which are capable of receiving a substance delivery device or devices at the distal end of the arm or arms.

20. A support frame as claimed in any one of claims 10 to 19 characterised in that support frame includes a locator to enable the substance delivery device to be readily located and removed from *in situ*.

21. A substance delivery device substantially as herein described with reference to and as illustrated by the accompanying drawings.

22. A pod substantially as herein described with reference to and as illustrated by the accompanying drawings.

23. A support frame substantially as herein described with reference to and as illustrated by the accompanying drawings.

09/529128

WO 99/18884 PCT/NZ98/00147

FIG 1

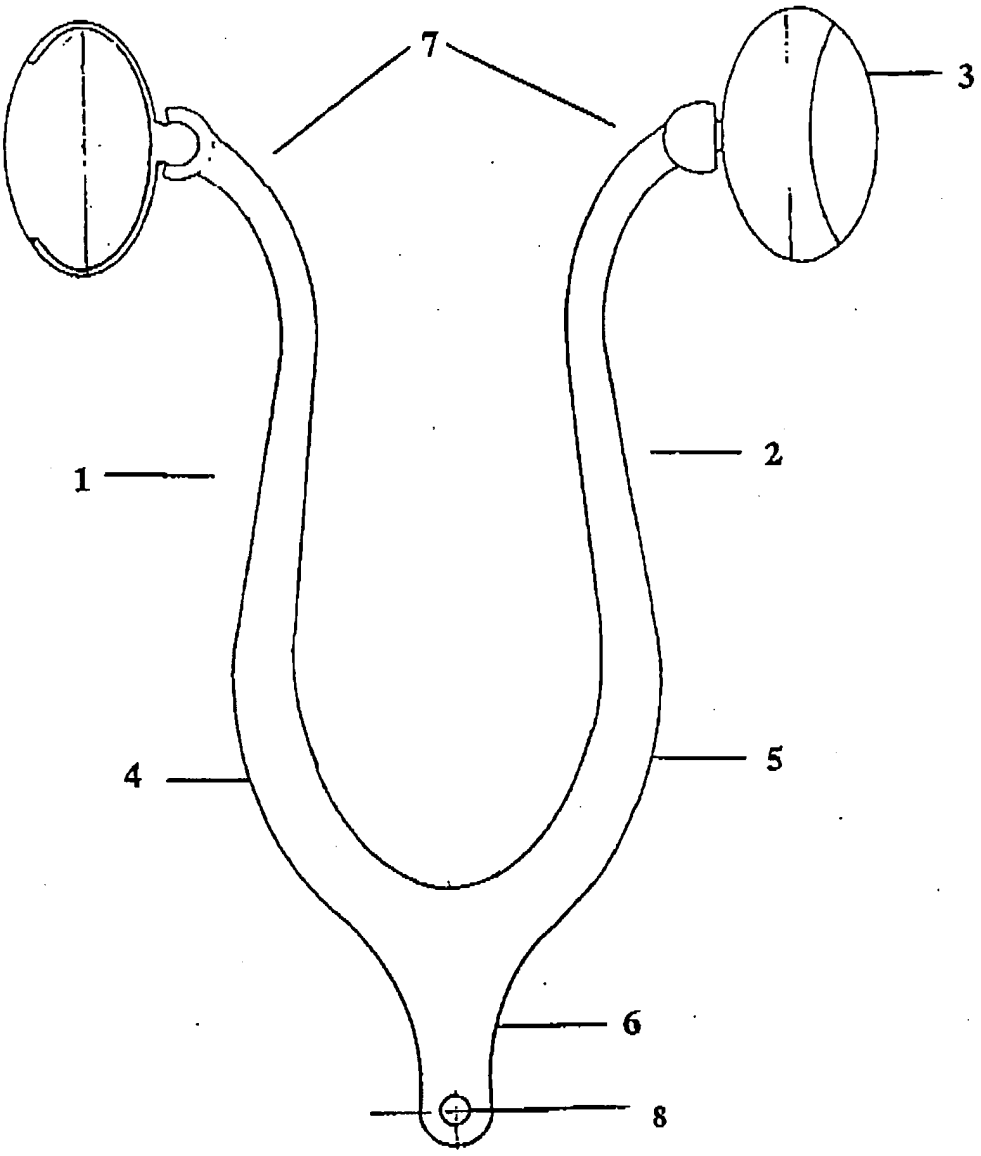
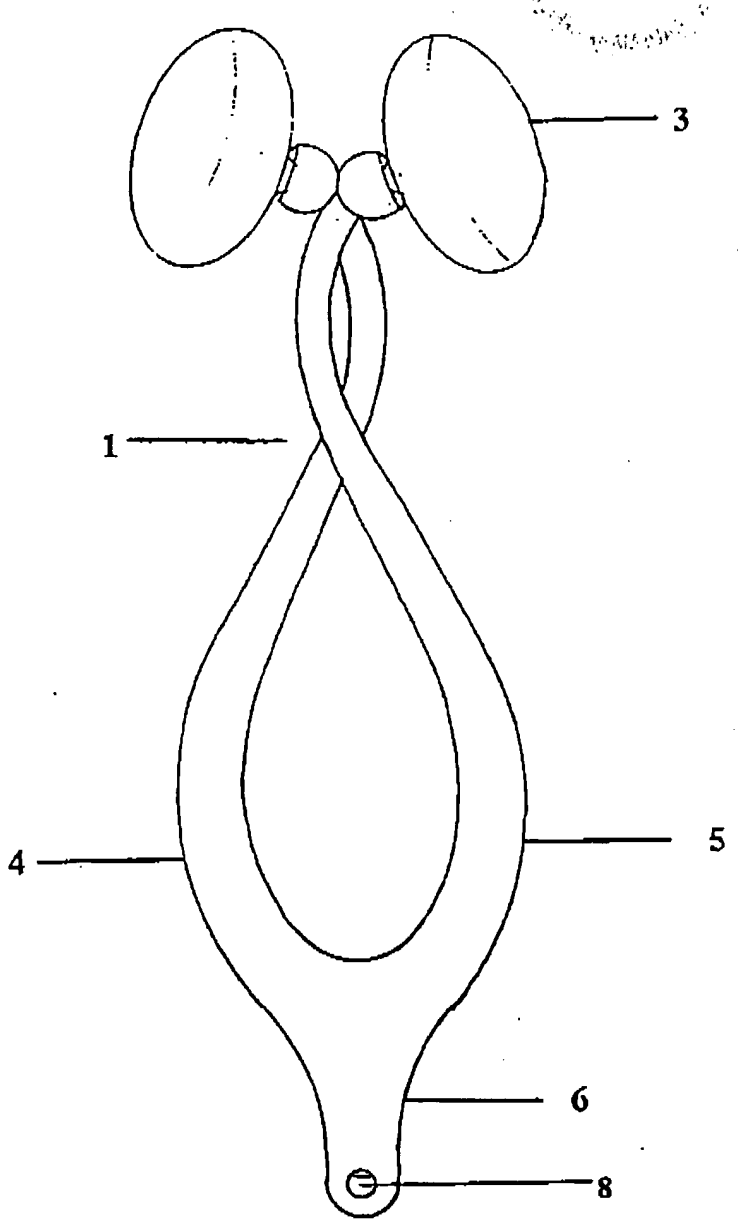


FIG 2



INTERNATIONAL SEARCH REPORT

International application No.
PCT/NZ 98/00147

A. CLASSIFICATION OF SUBJECT MATTER

Int Cl[6]: A61D 7/00, A61F 6/14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC: A61D 7/-; A61F 6/-

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
WPAT: frame, hold, support, retain, slow, sustain, release, deliver, osmosis, diffuse, elute, drug, substance, pharmaceutical, medicament, leach, IUD, intrauterine, device

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 93/19698 A1 (DARATECH PROPRIETARY LIMITED) 14 October 1993 Figure 2, abstract, page 4 lines 9-22	1-4,6,9-14,16,17,20
X	WO 96/01092 A1 (LEIRAS OY) 18 January 1996 Abstract, Figure 1	2,3,7
X	US 4341728 A (ROBERTSON et al.) 27 July 1982 Abstract, Figure 1	2,3,7,10-20

[X] Further documents are listed in the continuation of Box C

[X] See patent family annex

* Special categories of cited documents:

"A" Document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
12 March 1999	23 MAR 1999

Name and mailing address of the ISA/AU	Authorized officer
AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No.: (02) 6285 3929	**STEVEN WEISS** Telephone No.: (02) 6283 2466

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

United States Patent and Trademark Office
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Crystal Plaza 2
Washington, DC 20231
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 20 May 1999 (20.05.99)	
International application No. PCT/NZ98/00147	**Applicant's or agent's file reference** 15131/3X019
International filing date (day/month/year) 06 October 1998 (06.10.98)	**Priority date** (day/month/year) 10 October 1997 (10.10.97)
Applicant DUIRS, Graham, Francois	

1. The designated Office is hereby notified of its election made:

   [X] in the demand filed with the International Preliminary Examining Authority on:

   13 April 1999 (13.04.99)

   [ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

   [ ] was not

   made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO **34, chemin des Colombettes** **1211 Geneva 20, Switzerland**	Authorized officer C. Carrié
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/NZ 98/00147

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
WO	9319698	AU	37399/93	BR	9306162	EP	633753
		ZA	9302449				
WO	9601092	AU	24488/95	BR	9507667	CA	2189870
		CN	1151686	EP	768850	FI	943201
		ZA	9504368				
US	4341728	NONE					
EP	715847	AU	13969/92	AU	72867/94	BR	9201217
		CA	2065084	CN	1067810	CS	9201023
		EP	507629	FI	921493	HU	74907
		IL	101491	IL	118192	MX	9201539
		NO	921304	NZ	242225	PT	100345
		US	5277912	US	5562915	ZA	9202520
		JP	5097659				
AU	76074/74	CA	1037806	CH	604686	DE	2426944
		DK	6369/74	EG	11114	ES	432678
		FI	3523/74	FR	2253537	GB	1495735
		IL	46196	IT	1049334	JP	50094796
		NL	7415908	NO	744398	PH	15580
		SE	7415258	US	4034749	AT	9743/74
		DE	2402882	BE	823052	DE	2361206
		ZA	7407789	YU	3222/74		
WO	8804544	AU	10870/88	CA	1325564	CN	87108401
		EP	274794	NL	8603216		

END OF ANNEX

PATENT COOPERATION TREATY

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Date of mailing (day/month/year) 20 May 1999 (20.05.99)	
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   [ ] in a notice effecting later election filed with the International Bureau on:

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   made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

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Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38